AMENDMENTS TO THE CLAIMS

The following listing of claims replaces all prior listings and versions of claims in this application.

Claims 1 to 33. (Cancelled)

34. (Currently Amended) A method for sustained transdermal delivery of a therapeutic or immunogenic peptide, polypeptide or protein, the method comprising:

(i) generating a plurality of micro-channels in a region of intact skin of a subject by an apparatus that comprises: (a) an electrode cartridge comprising a plurality of electrodes; and (b) a main unit comprising a control unit, which is adapted to apply electrical energy to the electrodes when the electrodes are in vicinity of the stratum corneum of the skin, enabling ablation of the stratum corneum in the region beneath the electrodes, thereby generating the plurality of micro-channels;

(ii) affixing a patch to the region of skin in which said plurality of micro-channels is present, the patch comprising ~~at least one~~ a drug reservoir ~~layer, wherein the drug reservoir~~ layer ~~comprises~~ which is a matrix of a hydrophilic polymer ~~polymeric matrix~~ and a pharmaceutical composition comprising a therapeutic or immunogenic peptide, polypeptide, or protein; and

(iii) achieving a therapeutic concentration of the peptide, polypeptide, or protein in the subject's blood for at least 6 hours based on the delivery of said peptide, polypeptide or protein solely by diffusion from the patch through ~~the skin~~ said micro-channels to the blood.

35. (Previously Presented) The method according to claim 34, wherein the hydrophilic polymeric matrix is selected from the group consisting of hydrophilic biopolymers, hydrophilic synthetic polymers, derivatives and combinations thereof.

36. (Original) The method according to claim 35, wherein the biopolymer is selected from the group consisting of hydroxypropyl cellulose, carboxymethyl cellulose, hydroxyethyl cellulose, carrageenans, chitin, chitosan, alginates, collagens, gelatin, pectin, glycosaminoglycans (GAGs), proteoglycans, fibronectins, and laminins.

37. (Original) The method according to claim 36, wherein the biopolymer is selected from the group consisting of collagens and carrageenans.

38. (Previously Presented) The method according to claim 35, wherein the hydrophilic synthetic polymer is selected from the group consisting of polypropylene oxide, polyethylene oxide, polyoxyethylene-polyoxypropylene copolymers, polyvinylalcohol, polyvinylpyrrolidone, and polyurethanes.

39. (Original) The method according to claim 38, wherein the hydrophilic synthetic polymer is polyethylene oxide.

40. (Original) The method according to claim 34, wherein the drug reservoir layer is formulated in a form selected from a dry form, a semi-dry form, a hydrogel, and a solution.

41. (Previously Presented) The method according to claim 34, wherein the therapeutic or immunogenic agent is selected from the group consisting of growth factors, hormones, cytokines, water-soluble drugs, antigens, antibodies, fragments and analogs thereof.

42. (Original) The method according to claim 34, wherein the active therapeutic or immunogenic agent is selected from the group consisting of insulin, proinsulin, follicle stimulating hormone, insulin like growth factor-1, insulin like growth factor-2, platelet derived growth factor, epidermal growth factor, fibroblast growth factors, nerve growth factor, transforming growth factors, tumor necrosis factor, calcitonin, parathyroid hormone, growth hormone, bone morphogenic protein, erythropoietin, hemopoietic growth factors, luteinizing hormone, glucagon, clotting factors, anti-clotting factors, atrial natriuretic factor, lung surfactant, plasminogen activators, bombesin, thrombin, enkephalinase, relaxin A-chain, relaxin B-chain, prorelaxin, inhibin, activin, vascular endothelial growth factor, hormone receptors, growth factor receptors, integrins, protein A, protein D, rheumatoid factors, neurotrophic factors, CD proteins, osteoinductive factors, immunotoxins, interferons, colony stimulating factors, interleukins (ILs), superoxide dismutase, T-cell receptors, surface membrane proteins, decay accelerating factor,

viral antigens, transport proteins, homing receptors, addressing, regulatory proteins, analogs, derivatives and fragments thereof.

43. (Original) The method according to claim 42, wherein the therapeutic agent is growth hormone or insulin.

44. (Original) The method according to claim 34, wherein the drug reservoir layer comprises a collagen and human growth hormone.

45. (Original) The method according to claim 34, wherein the drug reservoir layer comprises a collagen and human insulin.

46. (Original) The method according to claim 34, wherein the drug reservoir layer comprises polyethylene oxide and human growth hormone.

47. (Original) The method according to claim 34, wherein the drug reservoir layer comprises polyethylene oxide and human insulin.

48. (Original) The method according to claim 34, wherein the drug reservoir layer comprises carrageenan and human growth hormone.

49. (Original) The method according to claim 34, wherein the drug reservoir layer comprises carrageenan and human insulin.

50. (Original) The method according to claim 34, wherein the patch further comprises at least one of the following layers: a backing layer, an adhesive, and a rate-controlling layer.

51. (Original) The method according to claim 34, wherein the pharmaceutical composition further comprises at least one component selected from the group consisting of protease inhibitors, stabilizers, anti-oxidants, buffering agents and preservatives.

52. (Cancelled).

53. (Cancelled).

54. (Previously Presented) The method according to claim 52, wherein the electrical energy is of radio frequency.

55. (Previously Presented) The method according to claim 51, wherein the buffering agent is selected from the group consisting of acetate buffer, phosphate buffer, and citrate buffer.

56. (Previously Presented) The method according to claim 34, wherein the pharmaceutical composition has a pH from about 3 to about 8.

57. (Previously Presented) The method according to claim 34, wherein the hydrophilic polymeric matrix is a cellulose derivative.

58. (Previously Presented) The method according to claim 34, wherein the patch comprises ethylene-vinyl acetate copolymer.

59. (Previously Presented) The method according to claim 34, wherein the therapeutic blood concentration of the peptide, polypeptide or protein is achieved for at least 10 hours.

60. (Previously Presented) The method according to claim 34, wherein the pharmaceutical composition comprises a sugar.

61. (Previously Presented) The method according to claim 60, wherein the sugar is selected from the group consisting of mannitol, lactose, sucrose, trehalose, and glucose.